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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHNADER HARRISON SEGAL & LEWIS, LLP
1600 MARKET STREET
SUITE 3600
PHILADELPHIA, PA 19103

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,484

Applicant(s)

DUPRAT ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in Paper No. 6 is acknowledged.
2. Claims 9-23 are pending and claims 17-23 are withdrawn from further consideration as being drawn to a non-elected invention. Applicant is reminded to cancel all claims drawn to non-elected subject matter.
3. Therefore, claims 9-16 are examined on the record.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. Claims 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 11 and dependents thereof recite the limitation "potassium transport channel" in claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112, 1st paragraph

6. Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified potassium permeable channel of SEQ ID No: 4 (TASK), does not reasonably provide enablement for any and all potassium permeable channels comprising more than 1 P domain and 3,4,5 or more than 6 transmembrane segments. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, practice the invention commensurate in scope with these claims:

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are drawn to an isolated TASK protein having a potassium permeable channel comprising more than 1 P domain and 3,4,5, or more than 6 transmembrane segments.

This includes a whole universe of polypeptides which have more than 1 P domain and 3,4,5, or more than 6 transmembrane segments.

The specification teaches (page 19, lines 15-21) that the invention provides for a TASK protein having outward rectifying channel properties (see page 24, line 17), wherein the TASK protein essentially acts as a "potassium ion selective "hole". One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any protein having more than 1 P domain and 3,4,5, or more than 6 transmembrane segments and applicant has not enabled all of these types of proteins because it has not been

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shown that these proteins are capable of functioning as that which is being disclosed.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, conservative replacement of a single "lysine" residue at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein (Burgess et al., J of Cell Bio. 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cellular Biology 8:1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Furthermore, the specification fails to teach what deletions, truncations, substitutions and mutations of the disclosed sequence can be tolerated that will allow the protein to function as claimed. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions. Residues that are directly involved in protein functions such as binding will certainly be among the most conserved (Bowie et

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al. Science, 247:1306-1310, 1990, p. 1306, col.2). Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to use any and all proteins having more than 1 P domain and 3,4,5, or more than 6 transmembrane segments. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

-The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Ketchum KA *et al* (Nature 1995 Aug;376(6542):690-695). The claim is drawn to

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a protein having a potassium permeable membrane comprising more than one P domain and 3,4,5, or more than 6 membrane segments. Ketchum *et al* teach a novel outward rectifying potassium channel with two pore domains and more than 6 membrane spanning segments.

9. Claims 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Price *et al* (US Patent No. 5,559,026). See above for limitations to claim 9.

Claims are further limited to the protein having two P domains and 4 transmembrane segments, which has outward rectification when the extracellular concentration is 2mM and no rectification when the extracellular potassium is 98mM, where in the potassium channel lacks intrinsic voltage, lacks voltage and time sensitivities, wherein the activity of the potassium channel is regulated by extracellular pH in the ranges of 6.5-7.8, and wherein the potassium channel exhibits 10% transport activity at pH 6.7 and 90% transport activity at pH 7.7. Price *et al* disclose a novel protein found in *C. elegans* that has two P domains and four transmembrane domains (see column 3, lines 13-19).

Although the reference does not specifically teach that the protein lacks outward rectifying capacity at 98mM, lacks intrinsic voltage, lacks voltage and time sensitivities, and regulated by extracellular pH, the claims are drawn to the product *per se* and inherently, such a protein would have the same characteristics. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not

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possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

10. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Reid JD *et al* (Receptors Channels 1996;4(1):51-62). See above for limitations to claim 9. Reid JD *et al* teach a protein with 8 possible transmembrane segments and two P domains.

11. Claims 9, 10 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Lesage *et al* (EMBO J 1996 March;15(5):1004-1011, IDS AR). See above for limitations to claim 9 and 10. Claim 12 is further limited to a channel that is characterized as being involved in background conductance. Lesage *et al* teach a protein having four transmembrane segments and two P domains. Lesage *et al* further teach that the protein is involved in background potassium ion conductance.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
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July 13, 2003

